

JUL 12 2002

**SOF-PACH™ Reusable Neurostimulation Electrodes
510(k) Summary**

The following information is submitted in accordance with the requirements of 21CFR807.92

Submitter's name: Anne Jen
CATHAY INTERNATIONAL LTD.
8F-3, NO. 29, CHUNGSHAN N.RD. SEC. 3,
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Contact person: Anne Jen

Date Prepared: 17 January 2002

Device Name: SOF-PACH™ Reusable Neurostimulation Electrodes

Comment/Usual Name: Neurostimulation Electrodes

Classification Name: Electrodes, cutaneous

Predicate devices: K963125 (M & R Manufacturing, Inc.)
K932849 (Pepin Mfg., Inc.)
K011411 (Pain Management Technologies)

Device description: SOF-PACH™ Reusable Neurostimulation Electrodes are non-sterile laminated, flexible structures composed of materials commonly used in this application:

First layer - Various cloths, tapes, etc. including Tricot/polyester fabric, polyethylene foam or a polypropylene substrate, coated with biocompatible adhesive.

Second layer - Electrically conductive carbon coated with or without Ag/AgCl, and Activated Carbon Mesh material.

Third layer - Biocompatible conductive hydrogel coupling media (CATHAY's Gel) which has passed the required skin sensitivity testing criteria as specified in the Tripartite Biocompatibility Guidance for Medical Devices and ISO 10993-1 requirements for skin contact. These tests include Cytotoxicity, Sensitization and Primary Skin Irritation Tests.

The electrodes are designed for single-patient/multiple application use. They have a low profile construction designed for comfort under clothing and utilize tan-tone fabric for reduced visibility. Because of the adhesive nature of the biocompatible hydrogel, no securing materials are required to secure the device to the patient's skin. The electrodes have two different types of contact points that can be used to link the stimulation device to the electrodes. These contact points are compatible with standard marketed Neurostimulation devices.

1. Lead wire assembly - 6" wire with .080 inch diameter recessed female socket connected to one side of the wire. The lead wire assembly is in compliance with the requirements of FDA performance standard 21 CFR Part 898
2. Male snap assembly - Two-part sensor and stud mated together.

Technological Characteristics: SOF-PACH™ Reusable Neurostimulation electrodes are technologically equivalent to the predicate devices. They are physically and technically similar to those currently being marketed for "Neurostimulation" i.e., TENS (Transcutaneous Electrical Nerve Stimulation), MENS (Microcurrent Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) and PGS (Pulsed Galvanic Stimulation).

Safety and Effectiveness: CATHAY considers their SOF-PACH™ Neurostimulation electrodes to be as safe and effective as the M&R Disposable Neurostimulation electrodes, the PMI Neurostimulation electrodes and the PMT Neurostimulation electrodes, which were previously found to be substantially equivalent via 510(k) Premarket Notifications. The safety issues analyzed were skin irritation. The effectiveness of the electrodes was determined by comparing impedance levels in point-to-point testing using a voltmeter.

The first safety issue considered was whether the gel, which is used to adhere the electrode to the skin and which is the only portion of the electrode to maintain skin contact, would cause any skin irritation. CATHAY's Gel has passed the required skin sensitivity testing criteria specified in the Tripartite Biocompatibility Guidance for Medical Devices and ISO 10993-1 requirements for skin contact. These tests include Cytotoxicity, Sensitization and Primary Skin Irritation tests.

Because there are no published performance standards for Neurostimulation electrodes, CATHAY uses impedance levels as the criteria for effectiveness testing. When measuring the electrodes' impedance, driven at 1 K-Hz, using a standard voltmeter, the point-to-point impedance testing for all manufacturers' electrodes (including SOF-PACH™) ranged from 125-250 ohms from the top center portion of the electrode to the underside of the outside edge. Once this testing was complete, it was determined that SOF-PACH™'s electrode impedance values were comparable to other marketed electrodes tested.

For the above reason, CATHAY considers its Reusable TENS/NMES electrodes to be as safe and effective as the predicate devices, as well as to multiple other TENS/NMES electrodes currently being marketed, including those manufactured by: Uni-Patch (K962910), Katecho Incorporated (K000870), MSB limited (K980229), Axelgaard (K983741), Selective Med Components, Inc. (K946230), Medtronic, Inc. (K875284), Medical Design & Manufacturing Corp. (K895604), and Labeltape Meditect, Inc. (K900656, K902719 and K894043).



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mrs. Anne Jen
Cathay International Ltd.
8F-3, No. 29, Chungshan N.Rd. Sec.3,
Taipei, Taiwan, R.O.C.

Re: K020735

Trade/Device Name: SOF-PACH Reusable Neurostimulation Electrodes
Models: CM4040, CM505, CM50100, and CM 75
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: June 11, 2002
Received: June 14, 2002

Dear Mrs. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

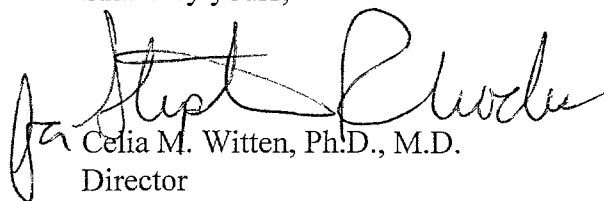
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic

Page 2 - Mrs. Anne Jen

product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) Page 2 - premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

K020735

**DEVICE NAME: SOF-PACH™ REUSABLE NEUROSTIMULATION
ELECTRODES**

INDICATIONS FOR USE:

SOF-PACH™ Reusable Cutaneous Neurostimulation Electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. SOF-PACH™ Reusable Electrodes are designed and intended to be used with marketed, Electrical Stimulators i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) or PGF (Pulsed Galvanic Stimulation).

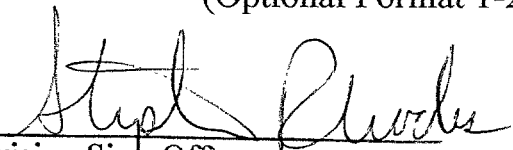
These electrodes will include the precaution statement: Federal Law restricts the device to sale by or on the order of a licensed practitioner or therapist.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use X
(Per 21 CFR 801, 109)

OR:

Over-the Counter Use _____
(Optional Format 1-2-96)


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020735